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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/801,864	03/08/2001	Archie Woodworth	SFP 5772 (1417Y P552)	6736

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EXAMINER
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HUYNH, LOUIS K

ART UNIT	PAPER NUMBER
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3721

DATE MAILED: 02/10/2004

11

Please find below and/or attached an Office communication concerning this application or proceeding.

## Office Action Summary

Application No.

09/801,864

Applicant(s)

WOODWORTH ET AL.

Examiner

Louis K. Huynh

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 07 November 2003.  
2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.  
3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-30 and 33-52 is/are pending in the application.  
4a) Of the above claim(s) 1-28 is/are withdrawn from consideration.  
5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.  
6) ☒ Claim(s) 29,30 and 33-52 is/are rejected.  
7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.  
8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.  
10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).  
11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
a) ☐ All b) ☐ Some \* c) ☐ None of:  
1. ☐ Certified copies of the priority documents have been received.  
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.  
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)  
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)  
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
Paper No(s)/Mail Date 9.  
4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_.  
5) ☐ Notice of Informal Patent Application (PTO-152)  
6) ☐ Other: \_\_\_\_\_.

## DETAILED ACTION

### *Election/Restrictions*

1. Claims 1-28 have been withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected inventions, there being no allowable generic or linking claim. Election was made **without** traverse in Paper No. 10.

### *Claim Rejections - 35 USC § 112*

2. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

3. Claims 46-52 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 46, line 6: "applying a sterilant a sterilized tip cap" is confusing. Perhaps the phrase should be: --applying a sterilant to a sterilized tip cap--.

### *Claim Rejections - 35 USC § 103*

4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

5. Claims 29, 34-37, 39, 40-52 are rejected under 35 U.S.C. 103(a) as being unpatentable over Heffernan et al. (US 5,620,425) in view of Reinhard et al. (US 6,065,270).

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With respect to Claims 29, 35 and 46, Heffernan discloses a method for filling a syringe including the steps of: providing a sterilized syringe body (1) of a suitable plastic (col. 4, lines 42-47) and having a nozzle end (2) and an open end (end 4); applying a sterilant to the syringe body (col. 6, lines 14-20) in order to transfer the sterilized syringe body to a class 100 sterile environment (col. 7, lines 34-36); filling the sterilized syringe body with an appropriate quantity of sterile water for injection (col. 7, lines 6-8); sealing the open end of the sterilized syringe body with an elastomeric component of a halobutyl-based elastomer (col. 5, lines 8-10 & col. 6, lines 22-23). The method of Heffernan meets all of applicant's claimed subject matter but lacks the specific teaching of the syringe body being of norbornene and ethylene copolymer.

However, Reinhard discloses a method for manufacturing a filled syringe body wherein the syringe body (2) is preferably formed from cyclic olefin copolymer that is known to include norbornene and ethylene. Since Heffernan teaches that the syringe body (1) can be made of any suitable plastic; therefore, it would have been obvious to an ordinary skilled person in the art, at the time the invention was made, to have modified the method of Heffernan by having formed the syringe body from norbornene and ethylene copolymer, as taught by Reinhard, since such material provide excellent barrier to water vapor in addition to having the required mechanical strength as well as being clear and transparent (Reinhard, col. 6, lines 52-63).

Regarding the limitation of the sterilant being applied as the sterilized syringe body being transferred to the sterile environment, Heffernan teaches that the syringe body may optionally be stored for a period of time prior to use and may optionally be sterilized (col. 6, lines 14-20). The stored syringe body must be sterilized in order to re-enter the

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sterile environment for the filling and assembling processes; therefore, it would have been obvious to an ordinary skilled person in the art, at the time the invention was made, to have modified the method of Heffernan by having provided a step of sterilizing the syringe body as the syringe body is transferred into the sterile environment so that the sterile environment is not contaminated and the filling and/or assembling processes can be kept under sterile condition.

With respect to Claim 46, the method of Heffernan also includes the steps of: applying a sterilant to a plunger (5) as the plunger is transferred to the sterile environment (col. 8, lines 23-30), applying a sterilant to a tip cap (3) as the tip cap is transferred to the sterile environment (col. 8, lines 23-30), sealing the nozzle end (2) of the syringe body (1) with the tip cap (3) (col. 7, lines 2-5), and sealing the open end (4) of the syringe body (1) with the plunger (5) to define a filled syringe assembly (col. 7, lines 9-11).

With respect to Claim 34, Heffernan discloses an optional step of exposing the syringe body to sterile filtered, deionized air (col. 6, lines 3-8). it would have been obvious to an ordinary skilled person in the art, at the time the invention was made, to have included the step of exposing the syringe body to sterile filtered, deionized air in order to reduce static charge of the syringe body and to maintain cleanliness of the syringe body.

With respect to Claims 35, 37 and 48, the method of Heffernan meets all of applicant's claimed subject matter but lacks the specific teaching of irradiating the

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sterilized syringe body with electron beam radiation. However, Heffernan teaches that components of the syringe assembly must be sterilized prior to entering the sterile environment (col. 7, lines 2-4) and the sterilizing method includes using irradiation. Since irradiation with high-energy radiation such as electron beam (beta) radiation is a well known method for sterilizing medical devices such as plastic syringe bodies and the electron beam radiation can be controlled and offers deep penetration into the object to be sterilized without deforming the object; therefore, it would have been obvious to an ordinary skilled person in the art, at the time the invention was made, to have modified the method of Heffernan by having irradiating the syringe body with electron beam radiation in order to thoroughly sterilize the syringe body with deep penetration without deforming the syringe body.

Regarding the limitation of the sterile water maintaining the pH from about 5.0 to about 7.0 for a predetermined time, the sterile water for injection must be stable and meet a certain requirements; therefore, if the sterile water is required to have a pH level from about 5.0 to about 7.0 for a predetermined time, the sterile water is expected to maintain such pH level at least for such predetermined time in order to fulfill such requirement.

With respect to Claim 36, the filling and sealing occur in the sterile environment (col. 7, lines 2-11).

With respect to Claim 38, it would have been obvious to an ordinary skilled person in the art, at the time the invention was made, as a common knowledge to have provided at least two electron beam sources for providing at least a dual beam of electron

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radiation to the syringe body in order to insure complete sterilizing all sides of the syringe body.

With respect to Claim 39, the sterility of the syringe body is maintained as the syringe body is transferred (col. 7, lines 35-36).

With respect to Claim 40, the method of Heffernan includes applying a sterilant such as steam (col. 7, lines 11-13) to the filled syringe assembly.

With respect to Claims 42 and 43, the exact time for filling the syringe body after irradiation is obvious to a skilled person in the art since time is not a critical factor in the process for filling the syringe; therefore, it would have been obvious to an ordinary skilled person in the art, at the time the invention was made, to have filled the sterilized syringe body immediately, within fifteen minutes or within five days as long as the syringe body is kept in the sterile environment and under the sterile condition for filling.

With respect to Claims 44 and 45, the sterile water is expected to maintain the pH level from about 5.0 to about 7.0 for at least about two years, if required.

With respect to Claims 41 and 49, the method of Heffernan including a step of sterilizing the filled syringe assembly (col. 7, lines 11-13) which meets all of applicant's claimed subject matter but lacks the specific teaching of the step of irradiating the sterile water for injection syringe with ultraviolet radiation. However, Reinhard discloses a

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process of manufacturing a filled syringe wherein the terminal sterilization is done by irradiating the filled syringe assembly with high-energy radiation. High-energy radiation is known to include gamma or beta (electron beam) radiation, infrared or ultraviolet radiation, microwave radiation, etc. Therefore, it would have been obvious to an ordinary skilled person in the art, at the time the invention was made, to have modified the method of Heffernan by having terminally sterilized the filled syringe assembly by irradiating the filled syringe assembly with high-energy radiation such as ultraviolet radiation, as taught by Reinhard, in order to prevent the sterile water from boiling.

With respect to Claim 47, the reference to Heffernan teaches that the syringe body (1) can be made of any suitable plastic including norbornene and ethylene copolymer since such blend is known in the art as one of the material used in injection molding of syringe body.

With respect to Claims 50-52, the sterile water for injection must be stable and meet a certain requirement as known in the art; therefore if the sterile water is required to have a pH level from about 5.0 to about 7.0 for a predetermined time, the sterile water is expected to maintain such pH level at least for such predetermined time, at least two years for example.

6. Claim 30 is rejected under 35 U.S.C. 103(a) as being unpatentable over the prior art as applied to Claim 29 above; and further in view of AAPA (Applicant Admitted Prior Art).



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The method of Heffernan meets all of applicant's claimed subject matter but lacks the specific teaching of the norbornene and ethylene copolymer having a heat deflection temperature at 0.45 Mpa from about 70°C to about 200°C.

However, AAPA discloses that norbornene and ethylene copolymers are well known and sold under trade names such as TOPAZ, ZEONEX, ZEONOR, CZ resin, APEL, etc. (page 6, lines 10-26), and the properties including heat deflection of these material can be modified to a preferred range is well within the knowledge of a skilled person in the art.

Therefore, it would have been obvious to a person with an ordinary skill in the art, at the time the invention was made, to have further modified the method of Heffernan by having provided the syringe body of a suitable plastic having the specific heat deflection ranges as claimed, as taught by AAPA, in order for the syringe body to be exposed at a high temperature without being deformed in shape.

7. Claim 33 is rejected under 35 U.S.C. 103(a) as being unpatentable over the prior art as applied to Claim 29 above; and further in view of Bayan et al. (US 4,978,714).

The method of Heffernan meets all of applicant's claimed subject matter but lacks the specific teaching of the halobutyl-based elastomer is a chlorobutyl-based elastomer.

However, Bayan teaches that chlorobutyl-based elastomer is a form of halobutyl-based elastomer (col. 5, lines 15-24) and the halobutyl-based elastomer is suitable for pharmaceutical products such as vial stopper, syringe tips and the like (col. 7, lines 23-30).

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Therefore, it would have been obvious to a person with an ordinary skill in the art, at the time the invention was made, to have further modified the method of Heffernan by having formed the elastomeric component from chlorobutyl-based elastomer, as taught by Bayan, since chlorobutyl-based elastomer is a form of halobutyl-based elastomer.

***Response to Arguments***

8. Applicant's arguments with respect to claims 29 and 35 have been considered but are moot in view of the new ground(s) of rejection.

***Conclusion***

9. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

10. A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

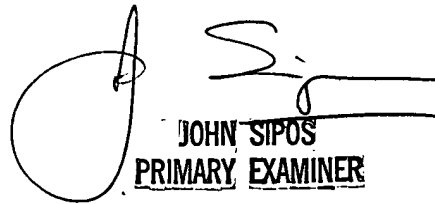
11. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Louis K. Huynh whose telephone number is (703) 306-5694. The examiner can normally be reached on M-F from 9:30AM to 5:00PM.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Rinaldi I. Rada can be reached on (703) 308-2187. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

LH  
February 4, 2004



JOHN SIPOS  
PRIMARY EXAMINER